

Translation

PATENT COOPERATION TREATY

PCT

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PCT/JP2003/014271



INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

10/551990

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference I04F1066	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/JP2003/014271	International filing date (day/month/year) 10 November 2003 (10.11.2003)	Priority date (day/month/year) 16 April 2003 (16.04.2003)
International Patent Classification (IPC) or national classification and IPC A61L 27/38, A61K 35/12		
Applicant INOUE, Kazutomo		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- | | |
|---|---|
| <input checked="" type="checkbox"/> Box No. I | Basis of the report |
| <input type="checkbox"/> Box No. II | Priority |
| <input checked="" type="checkbox"/> Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI | Certain documents cited |
| <input type="checkbox"/> Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> Box No. VIII | Certain observations on the international application |

Date of submission of the demand 06 October 2004 (06.10.2004)	Date of completion of this report 04 February 2005 (04.02.2005)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ The international application as originally filed/furnished
- ☐ the description:
- pages _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- pages _____, as originally filed/furnished
- pages* _____, as amended (together with any statement) under Article 19
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the drawings:
- pages _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 10-15

because:

- ☒ the said international application, or the said claims Nos. 10-15
relate to the following subject matter which does not require an international preliminary examination (*specify*):

See supplemental sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for said claims Nos. 10-15

- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the
Administrative Instructions in that:

the written form

- ☐ has not been furnished

- ☐ does not comply with the standard

the computer readable form

- ☐ has not been furnished

- ☐ does not comply with the standard

- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with
the technical requirements provided for in Annex C-bis of the Administrative Instructions.

- ☐ see Supplemental Box for further details.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III. 1.

The inventions set forth in claims 10 to 15
correspond to methods of treatment of the human body by
therapy (PCT Rule 67.1(iv)).

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-9, 16-17	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-9, 16-17	NO
Industrial applicability (IA)	Claims	1-9, 16-17	YES
	Claims		NO

2. Citations and explanations

The following documents are cited in the international search report:

- Document 1: M. Mitsuo et al., "Efficacy of Mesh Reinforced Polyvinylalcohol Tube as a Novel Device for Bioartificial Pancreas: A Functional Study of Rat Islets *In Vivo*, *Transplantation Proceedings*, Vol. 24, No. 6, 1992, pages 2939-2940
- Document 2: H. Inui et al., "Cold preservation of rat pancreatic islets just above the freezing point using University of Wisconsin solution," *Pancreas*, Vol. 23, No. 4, 2001, pages 382-386
- Document 3: S. Kanazawa et al., "Forskolin-stimulated adenylylcyclase activity: a marker to assess islet cell viability following cold storage in different solutions and to predict islet cell function following transplantation," *Cell Transplantation*, Vol. 8, No. 4, 1999, pages 383-388

Document 1 discloses a cellular preparation wherein islet cells are retained in a tube-shaped gelled polyvinylalcohol, and a method of preparing said preparation.

The inventions set forth in claims 1 to 9 and claims 16 and 17 of the present international application differ from the invention disclosed in document 1 in that a cellular preservative is also mixed into the preparation.

However, document 2 indicates that, by storing islet cells for transplantation in a UW cell preservation solution, the cells can be stably preserved even when the cells are stored at a temperature just above the UW solution freezing point.

Further, document 3 discloses the use of Euro-Collins solution or UW solution, which are both cell preservation solutions, for the stable preservation of islet cells for transplantation.

Thus, in order to improve the stability of islet cells in the invention disclosed in document 1, mixing in a solution known to be suitable for the stable preservation of islet cells, such as Euro-Collins solution or UW solution, would be obvious to a person skilled in the art.

Therefore, although the inventions set forth in claims 1 to 9 and claims 16 and 17 of the present international application are novel, they do not involve an inventive step in the light of documents 1 to 3.